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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,960	03/12/2004	Paul D. Graham	58327US004	9027
32692	7590	07/28/2005	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,960

Applicant(s)

GRAHAM ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed June 28, 2005 have been fully considered but they are not persuasive. The work of Anderson and Solis et al. provides clear motivation to combine the methodologies. Solis et al. states that it is unknown if a laser would re-create biological elements of the acute phase tattoo, indicating thoughts with that regard that would motivate one to investigate further. Anderson essentially, answers the question stating that the laser indeed "frees" the pigment granules, thus motivating one skilled in the art to combine the methodologies.

Claim Objections

Claims 11 and 22 are objected to because of the following informalities: they are improper Markush claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While many different IRM compounds are disclosed, the only testing was done with imiquimod, and those tests using a 5% imiquimod cream. No indication of testing or results with other IRMs is disclosed, bringing to question their liability in a method for tattoo removal. An "effective amount" is disclosed as

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"an amount that promotes clearance of a tattoo image (i.e., causes the image to fade and/or speeds disappearance, etc.). In certain embodiments, an effective amount of an IRM compound promotes full clearance (i.e., complete removal, disappearance) of the treated tattoo image. In other embodiments, an effective amount of IRM compound need only promote fading of the treated tattoo image". The disclosure further states "it is not practical to set forth generally the amount that constitutes an effective amount of an IRM compound. Those of ordinary skill in the art, however, can readily determine the appropriate amount with due consideration of such factors". Prior art on the use of IRMs for tattoo removal is limited, however, the cited Solis et al. reference clearly indicates, "more investigation is needed about dosage, duration or treatment, patient selection and other variables". The administration of the IRM compound is disclosed as an extremely broad range from "multiple doses administered multiple times per day" to "once per week" (page 13, lines 1-4). Thus, this methodology is deemed a nascent technology requiring more specific and useful teachings; See, e.g., Chiron Corp. v. Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a specific and useful teaching." The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

No test results were provided using the claimed IRM compound as an agonist of a TLR. While the disclosure states factually that certain IRMs can function as TLR agonists, no substantiation of their usefulness in the claimed methods is provided.

The question of an effective amount is further exacerbated by the cell disruption methodology lacking definite bounds. Lasers are disclosed as the preferred cell disrupter with

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several wavelengths disclosed, however, the only treatment fluence disclosed is "energy sufficient to disrupt dermal cells".

Considering the breath of the claims and the limited prior art and working examples, the predictability of results is uncertain and the level of ordinary skill in the art is likewise in question, thus requiring undue experimentation to achieve tattoo removal with the methods disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 cites "an effective amount" in line 3. The term lacks definite bounds and is indefinite.

Claim 16 cites "an amount of an IRM compound effective for removing a mature tattoo" in lines 2-3. The term lacks definite bounds and is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 11-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, "Regarding Tattoos - Is That Sunlight, or an Oncoming Train at the End of the

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Tunnel"; Arch Dermatology, Vol. 137, Feb. 2001; pgs. 210-212 in view of Solis et al.;

"Experimental Nonsurgical Tattoo Removal in a Guinea Pig Model with Topical Imiquimod and Tretinoin"; American Society for Dermatologic Surgery. Inc.; 28: 1 January 2002*, pgs. 83-87.

Anderson teaches tattoo removal using laser energy and that tattoos consist of phagocytosed sub-micrometer ink particles trapped in the lysosomes of phagocytic dermal cells, mostly fibroblasts, macrophages, and mast cells. When extremely intense (100 million W/cm²), brief (billionths of a second) light pulses (laser) are absorbed by these intracellular ink particles, they reach extreme temperatures. The particles fracture, undergo chemical changes, violently boil water in the cell cytoplasm, rupture the cells, and release laser-altered ink into the dermis. Some of this free ink is eliminated by lymphatic and transepidermal transport, but most of it is re-phagocytosed by somatic dermal cells within a few days. This laser may be a Q-switched Nd:YAG laser. Solis et al. disclose the removal of pigments using imiquimod (an immune response modifier) and further teach this therapeutic opportunity is potentially available if pigment granules can be removed before they become permanently engulfed by the dermal macrophages. Knowing that laser treatment yields "free" pigment granules, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the imiquimod, or other immune response modifier, as taught by Solis et al. with the laser treatment of Anderson to effect the free ink before it is re-phagocytosed. Solis et al. provide additional motivation to combine in the statement that it is unknown if lasers could "re-create... the acute phase tattoo", thus clearly suggesting that possibility had been considered and prompting one to investigate it further.

Regarding claims 2, 6-8 and 17-20, Solis et al. teach topical application of the compound and the claimed vehicles are well known in the art.

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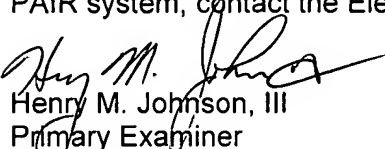
Regarding claims 3-5, there is no clear advantage to the order of the method disclosed leading one skilled in the art to experiment with various combinations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Primary Examiner
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